

EPA/OPP MICROBIOLOGY LABORATORY  
ESC, Ft. Meade, MD

Standard Operating Procedure  
for  
Quality Assurance Unit and its Functions

SOP QA-01-03

Date Revised: 01-10-06

Initiated By: \_\_\_\_\_ Date: \_\_\_\_/\_\_\_\_/\_\_\_\_

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Quality Assurance Officer

Approved By: \_\_\_\_\_ Date: \_\_\_\_/\_\_\_\_/\_\_\_\_

Print Name: \_\_\_\_\_  
Branch Chief

Effective Date: \_\_\_\_/\_\_\_\_/\_\_\_\_

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Withdrawn By: \_\_\_\_\_ Date: \_\_\_\_/\_\_\_\_/\_\_\_\_

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1.0 SCOPE AND APPLICATION:

- 1.1 The purpose of this SOP is to describe the functions of the Quality Assurance Unit (QAU) for the Office of Pesticide Programs (OPP), Microbiology Laboratory Branch (MLB). The Quality Assurance Officer (QAO) and alternate QAO shall function as the QAU.
- 1.2 The QAU ensures that all work conducted at the laboratory complies with the EPA Good Laboratory Practice Standards (GLPs), and adheres to guidance stipulated in the MLB Quality Management Plan, and the overall OPP Quality Assurance Management Plan.
- 1.3 The QAU is responsible for developing the Quality Management Plan for the MLB and interfaces with the OPP Quality Assurance Manager on quality assurance issues at the Divisional level.
- 1.4 The QAU shall function independently of personnel engaged in the direction and conduct of the laboratory procedures and studies. The QAU conducts audits and monitors laboratory activities to ensure integrity of study data.
- 1.5 The Branch Chief is responsible for coordination of technical audits performed by external parties

2.0 DEFINITIONS:

- 2.1 Team Leader = The team leader for the group of MLB microbiologists located at the Environmental Science Center, Fort Meade, MD.
- 2.2 GLP = Good Laboratory Practices (EPA GLP's are codified in 40CFR Part 160).

3.0 HEALTH AND SAFETY: Not applicable

4.0 CAUTIONS: None

5.0 INTERFERENCES: None

6.0 PERSONNEL QUALIFICATIONS:

- 6.1 The QAO and alternate shall complete the Agency's basic quality assurance course "Introduction to EPA Quality Systems." Continuing education is recommended by participating in the EPA Annual National Conference on Managing Environmental Quality Systems, and by attending additional workshops or courses offered by the EPA Office of Environmental Information Quality Staff or other organizations that may offer such training.

- 7.0 APPARATUS AND MATERIALS: None
- 8.0 INSTRUMENT OR METHOD CALIBRATION: Not applicable
- 9.0 SAMPLE HANDLING AND STORAGE: Not applicable
- 10.0 PROCEDURE AND ANALYSIS:

This section describes in detail the responsibilities of the Quality Assurance Unit

- 10.1 Conformance to GLPs: The QAU shall ensure compliance of laboratory work with GLPs. Specific responsibilities of the QAU are included in Section 160.35 (“Quality Assurance Unit”) of 40CFR, “Good Laboratory Practice Standards.”
- 10.2 Master Schedule: The QAU shall maintain a copy of the master schedule of all studies conducted at the laboratory. The schedules of testing activities will be developed by the Branch Chief in conjunction with the laboratory Team Leader and Senior Science advisor. These schedules will be used to develop auditing schedules. The Master Schedule will be updated regularly and monthly printouts will be archived.
- 10.4 Training Files: The Laboratory shall maintain a current summary of training and experience for each individual involved in the supervision or conduct of a study. These files shall contain, but not necessarily be limited to, the following: curriculum vitae, job descriptions, training certifications, and courses and seminars taken.
- 10.5 Audits: The QAU schedules and conducts internal audits for the MLB to ensure integrity of data.
  - 10.5.1 The QAU, Team Leader and the Senior Science Advisor would develop the audit schedule. The list will reflect all audits of laboratory operations and methods to be performed during the year, using the master schedule, project plans, and other factors as a guide. Laboratory records and books will also be audited. The Branch Chief shall be informed of the audit schedule.
  - 10.5.2 The annual technical audit of general laboratory operations will include a review of the systems in place for quality assurance, sample handling, preparation, analysis and data reduction. The audits will be based on current versions of SOPs followed in the Laboratory. Apparatus and supplies will be reviewed for conformance to SOP specifications. A sampling of calculations will be verified and documentation will be examined for accuracy and completeness.

- 10.5.3 The QAO has responsibility for study-in-progress audits at the Laboratory. The QAO may designate that certain audits be performed by other qualified QA/QC trained individuals, such as a contractor.
- 10.5.4 At the initiation of an announced audit, appropriate personnel (Study Director, Team Leader or others) shall be contacted and the audit purpose reviewed. The lead analyst will provide any necessary assistance, such as making personnel available, locating records, etc. Unannounced audits may also be conducted.
- 10.5.5 SOPs will be used as the audit standard against which operations and procedures will be evaluated. A checklist may also be used as guidance during the audit of general laboratory operations. The QAO may probe related areas in depth, as necessary, to satisfy the objective of the audit.
- 10.5.6 During the audit, if applicable, previous corrective action plans shall be verified.
- 10.5.7 At the completion of the audit, all observations and findings shall be reported to the Branch Chief, Team Leader, Senior Science Advisor or Study Director and the analyst(s) responsible for resolving the findings and initiating corrective action.
- 10.5.8 Audit Reporting: Audit reports will be formatted and processed as described below.
- 10.5.8.1 Audit Identification - An audit report shall be identified with the following information;  
Audit Title,  
Audit Number,  
Audit Date, and  
Performed by.  
The audit number will consist of the letters OPP-MICRO followed by the year and the sequential number of the audit performed that year. For example, the first audit performed in the lab in Calendar Year 2006 would be coded OPP-MICRO 2006-01.
- 10.5.8.2 Objective - Short paragraph(s) that outlines the objectives of the audit.
- 10.5.8.3 Scope - A brief description of when the audit was performed, what areas were reviewed and the names of key persons contacted.

- 10.5.8.4 Findings/Observations - Each finding or observation is listed. When used, a completed checklist shall be included. The QAO shall determine that no deviations from approved protocols and SOPs were made without proper authorization and documentation.
  - 10.5.8.5 Previous Audits Status - A short summary detailing the status of corrective action of previous audits.
  - 10.5.8.6 Conclusions/Recommendations - An overall summary of the audit with recommendations for a time-frame for corrective action.
  - 10.5.8.7 Checklists - Checklists that are used during the audit will be completed and attached to the report.
  - 10.5.8.8 Audit reports may be sent through electronic mail. Copies of audit reports shall be directed to the Branch Chief, Laboratory Team Leader and the analysts.
  - 10.5.8.9 Audit reports shall be issued within 30 working days of the conclusion of the audit.
  - 10.5.8.10 Responses to audits and schedules for completion of audits are due 30 days following the issuance of an audit report. Corrective actions must be completed within 60 days of issuance of the audit report. The Study Director/Team Leader is responsible for addressing each finding or observation. A reason for the noncompliance, as well as a plan for corrective action is required. If the QAO finds the plan of corrective action deficient, the QAO will discuss the situation with the Team Leader, Senior Science Advisor and/or the Branch Chief. If any unresolved issues remain, the QAO will raise them to the OPP QAM, who will discuss them with the Team Leader, Senior Science Advisor and/or the Branch Chief.
- 10.6 Revision of SOPs: All major revisions of SOP's shall follow SOP ADM-02, Preparation of SOPs, which describes the procedure, organization, and format of SOPs, their review and approval, revision, and storage. The QAU will maintain copies of all SOPs and Study protocols for all studies conducted at the MLB.
- 10.7 Final Reports. The QAU will review the final study reports to assure that the reported results accurately reflect raw data for the study. Also included with each

report is a Quality Assurance statement which specifies the audit dates and the dates when the audit findings were reported to the management and the study director. The Study Director will prepare and sign a statement that the study was conducted in compliance with GLP.

11.0 DATA ANALYSIS/CALCULATIONS: None

12.0 DATA MANAGEMENT/RECORDS MANAGEMENT:

12.1 Results of reviews of data and reports, findings from audits, and any other documentation of quality assurance activities, including quality assurance records required by GLPs, will be maintained according to SOP ADM-03, Records and Archives, and filed in the QAU's files located in Room D217, at the Environmental Science Center. These documents are subject to Agency's official records retention schedule.

13.0 QUALITY CONTROL/QUALITY ASSURANCE:

13.1 The OPP Microbiology Laboratory quality assurance issues are discussed and resolved with the Team Leader, Senior Science Advisor and Branch Chief, and if needed, with OPP QAM.

14.0 NONCONFORMANCE AND CORRECTIVE ACTION:

14.1 Based on audit findings, corrective actions must be completed within 30 working days of the audit report, or a schedule for completion of corrective actions must be prepared that would have all corrective actions scheduled to be completed within 60 working days of the date of the audit report.

15.0 REFERENCES:

15.1 EPA Good Laboratory Practice Standards, 40CFR Part 160.

16.0 FORMS AND DATA SHEETS: None